

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: }
Kyungyo Min et al. }
Serial No. 10/826,420 }
Filed: April 16, 2004 }
For: METHOD AND APPARATUS FOR }
COLLECTING AND PROCESSING BLOOD }

Examiner: Leslie R. Deak
Group Art No.: 3761
Confirmation No.: 9851

RESPONSE TO ADVISORY ACTION OF MAY 14, 2009

Sir:

In a Response dated April 28, 2009 (which addressed a final Office Action dated March 9, 2009), Applicant argued that claims 1, 3-7, 10, 13, and 20-31 of the above-identified patent application were patentably distinct from the prior art. In particular, Applicant described why independent claims 1, 20, and 28 are distinguishable from U.S. Patent No. 6,632,191 ("Headley").¹ In an Advisory Action dated May 14, 2009, the Examiner entered Applicant's arguments, but rejected them as follows:

[A]pplicants argue that the two systems disclosed in Headley (the Prior Art system and the Headley system) cannot be combined since the initial collection bag in the Prior Art system is used to collect and separate blood, rendering it functionally equivalent to the rotor 21 of the Headley system. However, the Examiner notes that filter 17 in the Prior Art system separates white blood cells from the collected red blood cells, providing a separation step not performed in initial collection bag 12. Accordingly, it is the position of the Examiner that Headley's two disclosed systems are properly combined to arrive at the claimed invention.

¹ Independent claims 1, 20, and 28 were rejected as being unpatentable over Headley in the March 9, 2009 Office Action.

For the reasons which follow, the arguments presented in the April 28, 2009 Response remain valid and it is respectfully requested that the claims be allowed.

All of independent claims 1, 20, and 28 recite methods wherein whole blood is flowed from a blood source to two locations. At least a portion of the whole blood in one of these locations is processed in that location, while processing of at least a portion of the quantity of whole blood in the other location does not begin before the source is disconnected.

The March 9, 2009 Office Action acknowledged that Headley fails to disclose a method of flowing whole blood into two locations. Indeed, Headley provides only one location (rotor 21) into which whole blood is flowed prior to component separation and subsequent removal of a blood component from the location. The March 9, 2009 Office Action pointed to the so-called "prior art system" illustrated in Fig. 1 of Headley as employing an "initial collection container" (bag 12) in which blood from a donor is processed after the donor has been disconnected from the system. The Action argued that the two systems taken together suggest that "a blood separation circuit may comprise both an initial collection bag and a separation chamber that are capable of holding collected blood before processing."

In the April 28, 2009 Response, Applicant argued that each system (i.e., Headley and the "prior art system") provides only one location into which blood is flowed and processed, rather than the two locations recited in each independent claim. The Response observed that: (1) the two systems described in Headley employ functionally identical processing locations and (2) the fundamental difference between the two systems is not their structure, but is instead methodological, in that the Headley system begins processing before the blood source is disconnected, whereas the "prior art system" disconnects the source before processing begins.

As quoted above, the Examiner responds in the Advisory Action by arguing that the filter 17 of the "prior art system" provides a separation step not performed in the bag 12. The filter incorporated in the "prior art system" is not unique, as the Headley system

itself includes a filter 17, as shown in Fig. 2 and described in column 4, lines 18-24 of Headley. The filter provides the same function in each system, which is to remove white blood cells from separated red cells. The presence of the filter in both systems does not contradict or diminish Applicant's argument that the bag 12 of the "prior art system" and the rotor 21 of the Headley system are functionally identical, but rather highlights the similarity of those two systems and the differences from the claimed invention. In particular, the Headley and "prior art" systems employ a single whole blood processing location and, although processing may take place at different times relative to the blood source's interconnection to the system, both produce a separated red cell material that is advantageously leukofiltered. Stated differently, one would not replace the filter in the "prior art system" with the rotor 21 of the Headley system or replace the filter in the Headley system with the bag 12 of the "prior art system" because the bag and rotor do the same thing as each other, while the filter does something entirely different. So, the replacement suggested in the Office Action is illogical and actually counter to the function, rationale, and purpose of each of the prior systems.

Further, the presence of a filter does not establish a second blood processing location inherent in either the "prior art system" or the Headley system. The Advisory Action indicates that "filter 17 in the Prior Art system separates white blood cells from the collected red blood cells, providing a separation step not performed in initial collection bag 12." This misstates the claimed subject matter, as all of the independent claims recite two locations for processing whole blood, rather than two different separation locations in general. It is clear that the filter 17 described in Headley interacts with only a blood component (separated red cells), rather than with whole blood. Headley column 1, lines 50-56 and column 4, lines 19-25. Hence, insofar as the pending claims are concerned, the "prior art system" and the Headley individually and together describe no more than: (1) flowing blood from a source into a single location, (2) processing the blood in that location, (3) removing separated red cells from the location, and (4) passing red cells through a leukocyte removal filter. There is no suggestion to incorporate or employ a second whole blood processing receptacle into